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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,322	06/07/2001	Ward Beryl Bowen JR.	87312.000003	8426

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EXAMINER

PAK, JOHN D

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/876,322

Applicant(s)  
Bowen et al.

Examiner  
John Pak

Art Unit  
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) 40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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Claims 1-41 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to a composition for accelerating in vivo oxidation of ethanol or methanol, classified in multiple subclasses in Classes 514 and 424, depending on the various composition components.
- II. Claims 40-41, drawn to a method for accelerating in vivo oxidation of ethanol comprising administering multivalent transition metal ion/complex and NAD<sup>+</sup> classified in multiple subclasses in Classes 514 and 424, depending on the specific structure of the administered components.

Applicant is further required to elect for examination purposes a single disclosed species of the multivalent metal ion or complex, such as vanadyl sulfate or potassium ferricyanide.

Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as in opioid addiction treatment, nutritional supplementation, or methanol oxidation acceleration.

Additionally, to search and examine both inventions would place an undue burden on the Examiner because of the nature of the Group I invention. To properly search Group I, the

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Examiner must review every pertinent document for coexistence or admixture of multivalent ion/complex and NAD<sup>+</sup>, regardless of use or functionality. Most of the documents may be completely irrelevant to ethanol oxidation utility. Given the extensive nature of the prior art involving these substances, to search and examine more than one invention as set forth above would place an undue burden on the Examiner if the restriction were not required.

For these reasons, the restriction requirement is deemed to be proper.

During a telephone conversation with Mr. Shaw on 9/23/2002 a provisional election was made with traverse to prosecute the invention of Group I, wherein the single disclosed species of the multivalent metal ion or complex is vanadyl sulfate, claims 1-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 40-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-39 will presently be examined to the extent that they read on vanadyl sulfate.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 37-39 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-3. When two claims in an application are duplicates or else are so close in content that

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they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are directed to the composition per se; therefore, recitation of ethanol or methanol oxidation acceleration, without more, does not distinguish the two compositions when they recite identical composition components.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is confusing in the independent claims 1 and 37 whether NAD<sup>+</sup> is merely one of the members of a Markush group, or a second ingredient that must be present in the composition. A proper and definite Markush group is recited as follows: "selected from the group **consisting of ... and .....**" Here, unclear Markush language is used and moreover, the placement of NAD<sup>+</sup> in the claim sentence makes it unclear whether it is a Markush member of a separate, second ingredient.

In claim 3, line 5, there is a missing right parenthesis for zirconium IV.

Applicant is advised that the combination of NAD<sup>+</sup> and vanadyl sulfate, with proper language correction as noted above for claim 1, is deemed to be allowable at this time. There is no claim directed solely to such subject matter, so no claim can be indicated as being allowable at this time.

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Examination of the claims will now continue to the extent that the claims read on the following next species: iron metal ion or complex.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 37-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vadgama et al. (WO 98/20332).

Vadgama et al. explicitly disclose a solution mixture that contains potassium ferricyanide and NAD<sup>+</sup>. See Examples 2 and 3 on pages 9-10.

While the composition disclosed by Vadgama et al. is not intended to be used for accelerating in vivo oxidation of ethanol or methanol, the composition per se is disclosed. It does not appear that Vadgama's composition contains such different components, in view of the various additives that are recited in applicant's dependent claims, that it would or could not function as required by applicant. Since the materials used by Vadgama et al. are analytical

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grade, Vadgama's composition is not precluded from applicant's use. Therefore, the claims are anticipated or at least rendered obvious within the meaning of section 103(a). See MPEP 2112, 2112.01.

Claims 1-2, 4-11, 15, 17-19, 22-23, 34-35, 37-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blass (US 5,053,396).

Blass explicitly disclose a composition that contains, inter alia, the following components: NAD<sup>+</sup>, iron ions, sodium bicarbonate, thiamine HCl, fructose, pyridoxine HCl, acetylsalicylic acid or ibuprofen (see column 5, lines 37-61). Blass' composition is specifically for treatment of acute or chronic symptoms associated with excessive ingestion of alcohol, most particularly ethanol (column 1, lines 7-12; claims 15-28). The composition is disclosed to help accelerate the breakdown of alcohol (paragraph bridging columns 2 and 3). With regard to dependent claims that recite quantities sufficient to provide in vivo concentrations in certain percentage range of in vivo molar concentration of ethanol, it is the Examiner's position that such language is so variable and dependent on external factors such as alcohol level of a person that the Blass's quantities are deemed sufficient (see column 5, lines 37-61 and claims 1-14).

The claims are thereby anticipated or at least rendered obvious within the meaning of section 103(a). See MPEP 2112, 2112.01.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1000